

**REMARKS / ARGUMENTS**

Reconsideration of this application is respectfully requested in view of the above amendments and below remarks.

**Rejections under 35 U.S.C. §112**

Claims 22-30 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Applicant has amended the claims in an attempt to overcome this rejection, in particular to provide appropriate dependencies between claims. Claim 22 has been amended to now be in independent form, and claims 28 and 29 no longer depend from withdrawn claims. Applicant has amended the claims to recite 'The brachytherapy positioning system' and have therefore fixed antecedent issues. Therefore it is requested that this rejection be withdrawn. The Examiner is thanked for pointing out the typographical errors.

**Rejection Under 35 U.S.C. § 102(b)**

Claims 1-5 and 9-10 were rejected under 35 U.S.C. § 102(b) as being anticipated by Williams, U.S. 5,913,813.

**Williams:**

Williams describes, in the Abstract: "An instrument for use in brachytherapy comprises a concentric arrangement of inner and outer distensible, spherical chambers disposed near the proximal end of a catheter body where one of the chambers is made to contain a radioactive material with the other chamber containing a radiation absorptive material, the apparatus

functioning to provide a more uniform absorbed dose profile in tissue surrounding a cavity created by the removal of a tumor. An alternative embodiment includes non-spherical inner and outer chambers whose respective walls are spaced equidistant over the entire surfaces thereof..."

In order to support a rejection under 35 U.S.C. §102, it is noted that *every* limitation in the claims must be shown or suggested by the references.

Applicant's claim 1 recites:

"...A spacing apparatus for use with a brachytherapy device for treating target tissue surrounding a surgical extraction site, comprising:  
an insertion member having a proximal end and a distal end;  
a spacing element disposed on the distal end of the insertion member,  
the spacing element having a predeterminable height and being adapted *to position a brachytherapy device ... at a distance apart from tissue ... the distance being equal to the height of the spacing element...*"

The Examiner relies on Williams as teaching the limitations of the claims, and recites several elements of Williams, but fails to show where Williams teaches that the spacing distance provided by the spacing element is equal to its height. The Examiner states that the spacing element or apparatus is balloon 36, and that the insertion member is catheter 12. Williams describes that an inner chamber 30 'is filled with radionuclide' (col. 2, lines 50-55).

Williams states, at column 2 lines 37-42:

"... Surrounding the spatial volume 30 is an outer chamber 34 defined by an outer polymeric film wall 36 that is appropriately spaced from the wall 32 of the inner chamber 30 when the two chambers are inflated..."

Applicant would respectfully assert that the 'spacing' provided by the balloon 36 is not equal to the *height* of the balloon 36, but rather the difference in circumferences between the inner chamber 30 and the balloon 36. As such, Williams neither describes nor suggests every element of the claimed invention, and it is therefore requested that the rejection be withdrawn.

Claims 4-5 and 9-10 serve to add further patentable limitations to their allowable parent claims, but are allowable for at least the reason of their dependency on an allowable claim.

#### Rejections under 35 U.S.C. §103

Claims 6-8 were rejected over Williams in view of Applicants specification. The Examiner states, at page 3 of the office action:

"... Williams discloses the claimed device except for the spacing element being disk shaped in the open position. Applicant states that it would be obvious to provide a spacing element of "any shape, such as square, oval, rectangular, etc. and can be flat or three dimensional" (page 10, lines 6-7) as determined by the desired use of the device. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the catheter as disclosed by Williams et al with a spacing element embodying any of a variety of shapes..."

35 U.S.C. §103 states:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to*

*which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

It is noted that Applicant's specification is *not prior art*. Applicant further objects to the mischaracterization of Applicant's recitation of equivalents in the specification, as a statement that they are 'obvious.'

It is noted that the portion of the text cited by the Examiner fails to overcome the inadequacies of Williams with regard to the claims. As such it is requested that the rejection be withdrawn.

Claims 7-11 were rejected under 35 U.S.C. §103(a) as unpatentable over Williams in view of Flexmedics Brochure. It is noted that the Flexmedics brochure cited by the Examiner fails to overcome the inadequacies of Williams with regard to the claims. As such it is requested that the rejection be withdrawn.

Although claims 22-30 were not examined due to 112 issues, it is noted that claim 22 also recites that 'a spacing apparatus comprising a spacing element having a predeterminable height and being adapted to position the brachytherapy device at a distance apart from tissue surrounding the surgical extraction site, the distance being equal to the height of the spacing...' Thus claim 22 and its dependent claims are patentably distinct from Williams.

**Conclusion**

In light of the above Remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case. If the Office should have any questions or other issues to discuss, please do not hesitate to contact the undersigned attorney.

Applicants believe no further fees or petitions are required. However, if any such petitions or fees are necessary, please consider this a request therefore and authorization to charge Deposit Account No. 50-2855 accordingly. Any deficiency or overpayment may also be applied to Deposit Account No. 50-2855.

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Respectfully submitted,

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